IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Application No.	**09/834,307**
Inventor:	Richard J. Whitbourne *et al.*
Confirmation No.	3036
Filing Date:	April 12, 2001
Title	TARGETED THERAPEUTIC AGENT RELEASE DEVICES AND METHODS OF MAKING AND USING THE SAME
Examiner	Micah Paul YOUNG
Art Unit	1618
Attorney Docket No.	32286-192724
Customer No.	26694

APPEAL BRIEF

Mail Stop: ***Appeal Brief - Patents***
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

In response to the Final Office Action dated May 28, 2008, and further to the Notice of Panel Decision from Pre-Appeal Brief Review mailed December 2, 2008, Appellant submits herewith an Appeal Brief in accordance with 37 C.F.R. § 41.37. Pursuant to 37 C.F.R. § 41.20(b)(2), please charge the required fee of $270.00 (small entity). Appellant submits herewith a Petition for Extension of Time within the fourth month under 37 C.F.R. § 1.136(a) and associated fee of $865.00 (small entity) under 37 C.F.R. § 1.17(a)(5). Any necessary additional fees are hereby authorized to be charged, and any overpayments credited to, our Deposit Account No. 22-0261, referencing our docket no. 32286-192724.

The Notice of Appeal was timely filed on September 29, 2008 (37 C.F.R. § 41.31(a)(3)), along with a Pre-Appeal Brief Request for Review pursuant to the "New Pre-Appeal Brief Conference Pilot Program" (1296 Off. Gaz. Pat. Office 67 (July 12, 2005), extended, 1303 Off. Gaz. Pat. Office 21 (February 7, 2006)).

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TABLE OF CONTENTS[1]

[1] The Table of Contents is included for reference purposes only and not to limit the issues to be reviewed on appeal.

I. REAL PARTY IN INTEREST – 37 C.F.R. § 41.37(c)(1)(i)

The real party in interest is ANGIOTECH BIOCOATINGS CORP. of HENRIETTA, NEW YORK, the owner of U.S. Patent Application No. 09/834,307 by virtue of assignment from the inventors, Richard J. Whitbourne, Daniel Hullihen, Michael R. Violante, Xianping Zhang, and Frank Wang recorded July 30, 2001, at Reel 012021, Frames 0546 and 0650. The real party in interest also includes parent company Angiotech Pharmaceuticals, Inc., of Vancouver, British Columbia, Canada.

II. STATEMENT OF RELATED APPEALS AND INTERFERENCES – 37 C.F.R. § 41.37(c)(1)(ii)

As of May 4, 2009, the filing date of this Appeal Brief, no other appeals, interferences or judicial proceedings are known to the Appellant or Appellant's legal representatives that will directly affect or will be directly affected by or have bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS – 37 C.F.R. § 41.37(c)(1)(iii)

Pending claims 23-67 and 69-83 have been finally rejected. Claims 1-22 and 68 remain canceled.

IV. STATUS OF AMENDMENTS – 37 C.F.R. § 41.37(c)(1)(iv)

No amendments or other responses have been filed subsequent to the Examiner's final rejection dated May 28, 2008, other than the Notice of Appeal and Pre-Appeal Brief Request for Review, which was timely filed on September 29, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER – 37 C.F.R. § 41.37(c)(1)(v)

A. The Independent Claims on Appeal – Claims 23, 43, 45, 50, 61, and 77

The claims generally relate to a medicated device as well as to methods of making and using such a medicated device. The device may include a substrate and a medicated polymeric coating bridging from one edge or surface of the substrate to another across an opening defined by adjacent edges or surfaces of the substrate. The following more detailed explanation of the claimed subject matter, with reference to the specification and drawings of the instant application, where applicable, is by way of example and for explanation only. The invention is not limited to the disclosed embodiments, and certain elements may be found in more than one of the disclosed embodiments.

Claim 23

Claim 23 recites a medicated device (*see, e.g.*, FIG. 1; page 5, lines 3-6). The medicated device comprises:

- a substrate comprising adjacent edges or surfaces in close proximity to each other defining an opening (*see, e.g.*, page 7, lines 14-17); and
- a coating bridging from one edge or surface to another across the opening (*see, e.g.*, page 7, lines 12-18), and said coating comprising at least one polymer and at least one therapeutic agent (*see, e.g.*, page 5, lines 4-6; page 13, lines 17-19),
- said therapeutic agent being at a loading of at least about 100 micrograms per square centimeter of coating (*see, e.g.*, page 5, lines 10-11).

Claim 43

Claim 43 recites a method for making a medicated device (*see, e.g.*, page 5, lines 3-6) comprising the steps of:

- providing a substrate comprising edges or surfaces in close proximity to each other defining an opening (*see, e.g.*, page 7, lines 14-17);
- providing a coating material comprising at least one polymer and at least one therapeutic agent (*see, e.g.*, page 5, lines 4-6; page 13, lines 17-19); and
- applying the coating material to said substrate to produce a coating bridging from one edge or surface to another across the opening (*see, e.g.*, page 7, lines 12-18),
- the therapeutic agent being at a loading of at least about 5 micrograms per square

centimeter of coating material (*see, e.g.*, page 5, lines 8-9).

Claim 45

Claim 45 recites a method of providing a therapeutic agent to a target tissue (*see, e.g.*, page 6, lines 16-21) comprising the steps of:

- providing a medicated device comprising a substrate comprising adjacent edges or surfaces in close proximity to each other defining an opening (*see, e.g.*, page 5, lines 3-6; page 7, lines 14-17),
- a coating bridging from one edge or surface to another across the opening (*see, e.g.*, page 7, lines 12-18),
- and said coating containing at least one polymer and at least one therapeutic agent and comprising one or more layers (*see, e.g.*, page 5, lines 4-6; page 6, lines 11-12; page 7, lines 26-27; page 13, lines 17-19); and
- inserting the medicated device into the target tissue to provide therapeutic benefit (*see, e.g.*, page 6, lines 9-11),
- wherein a therapeutic amount of said therapeutic agent diffuses into the tissue at least about one centimeter from said device (*see, e.g.*, page 5, lines 13-15; page 5, lines 21-25).

Claim 50

Claim 50 recites a medicated device (*see, e.g.*, FIG. 1; page 5, lines 3-6) comprising:

- a substrate suitable for implantation into a patient's body (*see, e.g.*, page 5, lines3-4) and comprising adjacent edges or surfaces in close proximity to each other defining an opening (*see, e.g.*, page 7, lines 14-17); and
- a formulation comprising at least one polymer and at least one therapeutic agent (*see, e.g.*, page 5, lines 4-6; page 13, lines 17-19), the formulation bridging from one edge or surface to another across the opening (*see, e.g.*, page 7, lines 12-18),
- the therapeutic agent being at a loading sufficient to deliver a therapeutically effective quantity of the therapeutic agent when implanted in the patient's body (*see, e.g.*, page 5, lines 5-6 and 13-14).

Claim 61

Claim 61 recites a medicated device (*see, e.g.*, FIG. 1; page 5, lines 3-6) comprising:

- a substrate comprising adjacent edges or surfaces in close proximity to each other defining an opening (*see, e.g.*, page 7, lines 14-17); and
- a coating bridging from one edge or surface of the substrate to another across the opening (*see, e.g.*, page 7, lines 12-18), and
- said coating comprising at least one polymer and at least one therapeutic agent at a loading sufficient to deliver a therapeutically effective quantity of the therapeutic agent when implanted in a patient's body (*see, e.g.*, page 5, lines 4-6; page 5, lines 13-14; page 5, lines 21-24; page 13, lines 17-19).

Claim 77

Claim 77 recites a medicated device (*see, e.g.*, FIG. 1; page 5, lines 3-6) comprising:

- a therapeutic agent (*see, e.g.*, FIG. 1 elements 16; page 5, lines 5, 14, and 23);
- means for containing the therapeutic agent (*see, e.g.*, FIG. 1 coating 14; page 5, lines 4-6; page 5, lines 22-23; page 13, lines 17-19); and
- means for providing structural support to the containing means (*see, e.g.*, FIG. 1 substrate 12; page 5, lines 3-5 and 21-22; page 6, lines 22-24; page 7, lines 12-18 and 22-25; page 13, lines 17-19),
- wherein the containing means bridges from one portion of the structural support providing means to another portion of the structural support providing means (*see, e.g.*, page 7, lines 12-18),
- wherein the therapeutic agent is at a loading sufficient to deliver a therapeutically effective quantity of the therapeutic agent in a patient's body when the device is implanted therein (*see, e.g.*, page 5, lines 4-6; page 5, lines 13-14; page 5, lines 21-24; page 13, lines 17-19).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL – 37 C.F.R. § 41.37(c)(1)(vi)

A. Whether claims 23-52, 56-59, 61-65, 67, 69-71, 74, 76-78, and 80-83 are unpatentable under 35 U.S.C. § 103(a) as being obvious in view the proposed combination of U.S. Patent No. 5,980,550 to Eder *et al.* and U.S. Patent No. 6,110,483 to Whitbourne *et al.*

B. Whether claims 50, 53-55, 60, 61, 66, 72-75, 77 and 79 are unpatentable under 35 U.S.C. § 103(a) as being obvious in view the proposed combination of Eder and Whitbourne, further in view of U.S. Patent No. 6,335,029 to Kamath *et al.* and U.S. Patent No. 5,589,120 to Khan *et al.*

VII. ARGUMENT – 37 C.F.R. § 41.37(c)(1)(vii)

A. Brief Statement of the Argument

The Examiner relied on an erroneous reading of the Eder reference, and has otherwise failed to establish a *prima facie* case of obviousness. Moreover, Appellant's arguments and evidence submitted in the response filed February 22, 2008, rebutted the Examiner's arguments of obviousness. Consequently, the claims should not be rejected as obvious in view of the references. More particularly, first, the Examiner is simply wrong that Eder, in particular the crude cartoon of FIG. 2, teaches or suggests "a coating bridging from one edge or surface of the substrate to another across the opening." Second, the Chamberlain Declaration establishes how FIG. 2 would be read by one of ordinary skill in the art (*see* Section VII(B)(1)(b) on pages 12-14 below), and explains how the Eder reference, properly read, is quite different from the claimed invention. Third, in the Final Office Action, the Examiner improperly disregarded Appellant's arguments and evidence and failed to accord them due weight in reconsidering the patentability of the claimed invention. Fourth, the Examiner misreads the written disclosure of Eder, which is inconsistent with the Examiner's interpretation of FIG. 2, and also misreads Whitbourne. Accordingly, all the rejections should be reversed.

B. The Examiner Improperly Rejected Claims 23-52, 56-59, 61-65, 67, 69-71, 74, 76-78, and 80-83 Under 35 U.S.C. § 103(a) Over Eder and Whitbourne

In numbered paragraphs 3-8 on pages 2-5 of the Final Office Action dated May 28, 2008, claims 23-52, 56-59, 61-65, 67, 69-71, 74- 76-78, and 80-83 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,980,550 to Eder *et al.* ("Eder") in view of U.S. Patent No. 6,110,483 to Whitbourne *et al.* ("Whitbourne"). The rejection is respectfully traversed and appealed. Reversal of the rejection is respectfully requested.

1. Independent Claims 23, 43, 45, 50, 61, and 77

Claims 23, 43, 45, 50, 61, and 77 are not obvious in view of the proposed combination of Eder and Whitbourne. Claim 61, for example, recites:

> A medicated device comprising:
> ***a substrate comprising adjacent edges or surfaces in close proximity to each other defining an opening***; and

> ***a coating <u>bridging</u> from one edge or surface of the substrate to another across the opening***, and said coating comprising at least one polymer and at least one therapeutic agent at a loading sufficient to deliver a therapeutically effective quantity of the therapeutic agent when implanted in a patient's body.

(emphasis added). Thus, claim 61 requires, inter alia, "a coating bridging from one edge or surface of the substrate to another across the opening." Claims 23, 43, 45, 50, and 77 each recite a similar feature.

a. <u>The Examiner Misread FIG. 2 of Eder as Teaching "Bridging"</u>

The Final Office Action cites the schematic cartoon depicted in FIG. 2 of Eder as ostensibly teaching or suggesting the recited "bridging." Specifically, in numbered paragraph 4 on pages 2-3, the Final Office Action states:

> The implant has a coil shape where the edges of the coils form opening [*sic*] between them. The edges are bridges [*sic*] by the coating material (Figure 2 204). The coating connects the edges of the coils (Figure 2).

To the contrary, Eder does <u>not</u> show, teach, or suggest any "bridging." Although drawings and pictures can be used as prior art where they clearly show the claimed structure, it is also well established that the teachings of all relevant references must be evaluated and applied "on the basis of what they ***reasonably*** disclose and suggest to one skilled in the art." *In re Aslanian*, 590 F.2d 911, 914, 200 USPQ (BNA) 500 (CCPA 1979) (quoting *In re Baum*, 374 F.2d 1004, 1009, 153 USPQ 190, 195 (CCPA 1967); *see also Ex Parte Deok-Kee Kim et al.*, 2009 WL 505513 at *5 (Bd.Pat.App. & Interf. Feb. 26, 2009). As more particularly described below, the schematic cartoon of Eder's FIG. 2 does not reasonably disclose or suggest the claimed structure (i.e., bridging), especially in the context of Eder, when taken *as a whole* (i.e., including both the written disclosure and the drawings). Simply put, Eder cannot be reasonably read to teach or suggest a coating bridging from one edge or surface of the substrate to another across the opening.

b. <u>The Chamberlain Declaration Establishes that Eder's Teaching Differs from the Claimed Invention</u>

The record establishes that FIG. 2 of Eder is a flawed schematic illustration or cartoon of the helically wound coil 202 having an inner coating 204 and an outer coating 206 described, for example, in column 4, lines 12-14 and 58-62. FIG. 2, which is expressly stated as not being to scale (*see* column 4, line 9), ostensibly shows a side perspective view of the coil 202 with a cross-section of the coating thereon to illustrate the first and second layers 204, 206. The three-dimensional nature of the coil, however, does not appear to have been taken into account when the cross-section of the dual-layer coating was added by the draftsperson.

Appellant submitted a Declaration under 35 C.F.R. § 1.132 of Ms. Alexandra M. Chamberlain, with the response filed February 22, 2008 to show the error in the Office's interpretation of the purported teachings of Eder. A copy of Ms. Chamberlain's Declaration is attached hereto.

Based on a fair and reasonable reading of Eder, it is Ms. Chamberlain's opinion that FIG. 2 does not teach or suggest "bridging." In particular, based on a reasonable understanding of that which is described and depicted in Eder as a whole, a proper side perspective view of the coil showing the two-layer coating in cross-section would actually look something like that shown in the drawing attached to her declaration as **Appendix B**. Clearly, the two-layer coating does not "bridge" from one edge or surface of the coil to another across the open area between the windings.

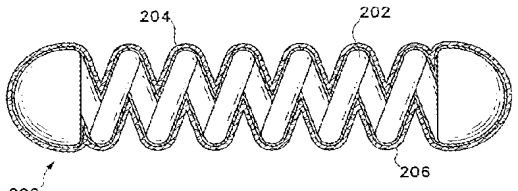
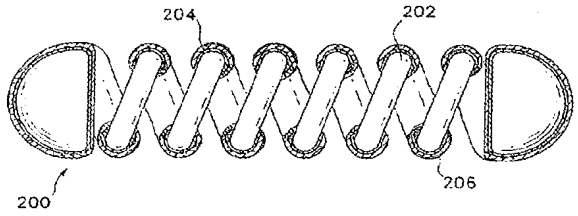


FIG. 2

(As in Eder)



(As attached to Chamberlain Declaration as Appendix B)

The drawing in **Appendix B** was generated by the Appellant based on a reasonable reading of the disclosure of Eder, as a more realistic sketch of Eder's device than the original schematic cartoon sketch. The Examiner places undue weight on the flawed schematic of FIG. 2. When read properly, in the context of the written description, Eder does not teach, show, or suggest a coating bridging from one edge or surface of the substrate to another across the opening.

c. The Examiner Improperly Ignored Declaratory Evidence

In finally rejecting the claims, the Examiner applied improper legal standards and failed to give due weight and consideration to the Declaration submitted to overcome the Examiner's incorrect interpretation of Eder. Applying proper standards, Eder, alone or in combination with Whitbourne, does not support a prima facie rejection, and the evidence is sufficient to rebut a prima facie case of obviousness.

The Chamberlain Declaration, submitted under Rule 1.132 with the February 22, 2008 Response, includes a sketch of what cartoon/schematic FIG.2 of Eder, properly interpreted, teaches, and concludes that Eder did not show a bridging coating (*see* para. 6-8 and Appendix B). However, on pages 7-9 of the Final Office Action, the Examiner clearly erred by improperly discrediting the "correct" schematic (Appendix B of the Chamberlain Declaration), stating that it "***has no bearing whatsoever on the patentability of the claims***." (emphasis added). Instead, ignoring the evidence in the Declaration to the contrary, the Examiner relied on a mistaken belief that Eder's FIG. 2 implicitly shows bridging.

The Examiner improperly gave no weight to Appendix B of the Chamberlain Declaration. Such evidence cannot be completely disregarded. Opinion testimony is a form of evidence having probative value and must be given some weight. *See* M.P.E.P. § 716.01(c)(III). In this case, the "correct schematic" in Appendix B was based on a fair reading of Eder's entire disclosure by one familiar with the technology. *See* para. 8 of the Declaration. The Chamberlain declaration and Eder's disclosure itself both provide factual evidence that Eder does not teach or suggest a bridging coating. It is clear error for a decision on patentability to be made based without consideration of all the evidence, including evidence submitted by the Appellant. *See* M.P.E.P. § 2142. Accordingly, when the Chamberlain Declaration is properly given its due weight, the so-called "correct schematic" does, in fact, bear on the patentability of the claims and demonstrates that the Examiner's interpretation of FIG. 2 of Eder is unreasonable and clearly erroneous.

Pages 6-7 of the Final Office Action states that the Chamberlain Declaration is "insufficient." The arguments and evidence presented in Appellant's response submitted February 22, 2008, were improperly ignored by the Examiner. The Examiner's analysis is clearly erroneous.

- *"The Declaration is not commensurate in scope with the instant claims and provides no direct actual comparison between the prior art."* (Final Office Action, page 6.)

To the contrary, the declaration is commensurate in scope with the claims and does, in fact, directly compare Eder and the claims. For example, in numbered paragraph 5 of the declaration, declarant Chamberlain points to independent claims 23, 43, 45, 50, 61, and 77 as reciting a coating "bridging" from one edge or surface to another across an opening. Then, in numbered paragraph 6, declarant Chamberlain outlines how and why Eder fails to teach or suggest any "bridging." Thus, the declaration is commensurate in scope with the claims and provides a direct comparison of the claims and Eder.

- *"The Declaration provides a theoretical schematic drawing showing what is alleged as actual "correct" interpretation of the Eder drawing. The Declaration presents no accompanying statement form the Eder inventors in support of this allegation, or any evidence to support this drawing other the opinions of the instantly named inventors. The arguments in the Declaration provide no solid evidence to support the proposed drawing."* (Final Office Action, pages 6-7.)

This statement is wrong on several levels. First, the drawing provided in Appendix B of the Chamberlain Declaration is merely an illustration of the text of the Declarant's description of the Eder patent, to demonstrate the improper reading by the Examiner and to suggest the proper reading of FIG. 2. The Declaration provides ample "solid evidence to support the proposed drawing." Also, the entire disclosure of Eder provides further evidence to the same effect as the Chamberlain Declaration. *See* the February 22, 2008 Response, pages 12-13 regarding the text of the Eder declaration. The Examiner's implied invitation to have the Eder inventors submit a declaration is based on another legal error – the correct standard is how a person of ordinary skill would read the reference, not how the reference's authors would read it, and not what its authors intended. Finally, the Examiner is incorrect in concluding that the Chamberlain Declaration is by an inventor. Ms. Chamberlain is not a named inventor in this application.

- *"The Declaration also provides no comparison between the actual drawing or invention of the Eder patent and the invention of the instant claims."* (Final Office Action, page 7.)

As noted above, paragraphs 5-6 of the Chamberlain Declaration provide a direct comparison and demonstrate the significant differences between the claims and Eder.

In view of the foregoing, the Appellant respectfully submits that the Examiner committed clear error in failing to give the declaration due weight and consideration. Additionally, the Examiner misunderstood or failed to read the declaration fairly. The Appellant respectfully

submits that the Chamberlain Declaration is, in fact, sufficient to rebut the Examiner's position as to what Eder reasonably teaches or suggests to one skilled in the art.

Reversal of the rejection is respectfully requested.

d. The Text of the References is Inconsistent with the Examiner's Interpretation

The written disclosure of Eder teaches away from the interpretation of FIG. 2 espoused in the Final Office Action, i.e., that the coating 204, 206 "bridges" the openings created between the individual windings of the coil 202. In column 3, lines 44-46, Eder states that "[p]referably, the inner and outer coatings do not affect the shape of said vaso-occlusive member after deployment." *See also* column 5, lines 61-63 and claim 14. This statement demonstrates that the Office's proposed interpretation of FIG. 2 is incorrect. The clear textual statement should be weighted more heavily than an incorrect, or at best ambiguous schematic cartoon that was not intended to depict the feature at issue here.

The Examiner's reading into Eder's FIG. 2 of "bridging" between individual windings of the coil 202 is incorrect because such bridging would affect the shape of the coil by, for example, creating a cylindrically shaped device. Accordingly, a fair and reasonable reading of Eder does not permit FIG. 2 to be interpreted as teaching or suggesting any "bridging" of the coating.

In numbered paragraph 5 on pages 3-4, the Final Office Action also states, citing column 4, lines 18-30 of Whitbourne, that "[t]hough silent to the specific design of the substrates regarding their edges and surfaces, the coating is a continuous coating over each surface." The Final Office Action then states that "Applicant is invited to provide evidence that the continuous coating of the invention [does not] cover the edges and bridge the surfaces." Final Office Action, page 4. It is respectfully submitted, however, that it is the Examiner that bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. The Appellant is under no obligation to submit evidence that the coating disclosed in Whitbourne does not "cover the edges and bridge surfaces." Nevertheless, the cited portion of Whitbourne only states, in relevant part, "a thin continuous layer over the substrate," and the coating is later described at column 7, lines 15-17 as "a continuous ***surface*** layer." The reference does not teach edges in close proximity and the ordinary meaning of "continuous" does not, by itself, teach or suggest "bridging." Thus, contrary to the Examiner's position, because Whitbourne does not describe coatings on substrates

with edges in close proximity to each other, it cannot teach or suggest a coating that bridges openings.

For at least the foregoing reasons, the Appellant respectfully submits that the Examiner's alleged *prima facie* case of obviousness has been rebutted.

2. Claims 23, 24, 69-71, and 80-83

Claims 23, 24, 69-71, and 80-83 recite specific loading amounts for the therapeutic agent. Neither one of Eder or Whitbourne, alone or in combination, is believed to teach or suggest the recited loadings. In addition to the foregoing deficiencies in Eder, the Final Office Action also acknowledges that Eder is "silent to the active agent loading of the implant." Page 3, numbered paragraph 4. This is apparently in reference to the recitations in various claims of a particular loading amount of the therapeutic agent in the coating. The Final Office Action states, however, that "[t]his loading is well known in the art" and cites Whitbourne as purportedly supporting this assertion. *Id.* More specifically, the Final Office Action states that "[t]he coating composition has a thickness of about less than 50 microns" (citing column 7, lines 15-20 of Whitbourne) and argues that "[a]ccording to applicant's specification a 10-micron thick coating would correspond to a 1000 microgram/cm^3 [*sic*]" such that "[t]he thickness of this coating would possess a loading amount well within the limits of the claimed invention." Page 3, numbered paragraph 5.

In response, the Appellant respectfully submits that neither Eder nor Whitbourne, alone or in combination, teaches or suggests the recited loading amounts and further submits that the proposed deductive reasoning is both unclear and unsupported. Notwithstanding the fact that Whitbourne purportedly discloses that the "coatings of the invention may be thin, on the order of 2 to 100 microns, preferably less than about 50 microns" (column 7, lines 15-16), there is nothing in Whitbourne or Eder that supports the assertion in the Final Office Action that such a coating would possess a loading amount "well within the limits of the claimed invention." Additionally, the Final Office Action presents no support in the cited references for the statement that "a 10-micron thick coating would correspond to a 1000 microgram/cm^3" loading (Final Office Action, page 3, numbered paragraph 5). This statement follows a citation to "applicant's specification" and, in this regard, the Final Office Action appears to be improperly attempting to use the instant disclosure to reach a hindsight conclusion which is entirely unsupported by the applied references, Eder and Whitbourne. Accordingly, the Appellant respectfully submits that neither Eder nor Whitbourne, alone or in combination, teaches or suggests the loading amounts recited in at least claims 23, 24, 69-71, and 80-83. Reversal of the rejection is respectfully requested.

3. Dependent Claim 28

Dependent claim 28 recites that the substrate is a perforated wafer or wire mesh. Eder and Whitbourne do not disclose such substrates. Whatever the reading of Eder and its FIG. 2, it does not teach these substrates, and the Examiner has not made out a prima facie case of obviousness for these claims. Reversal of the rejection is respectfully requested.

C. The Rejection of Claims 50, 53-55, 60, 61, 66, 72-75, 77 and 79 Under 35 U.S.C. § 103(a) Over Eder, Whitbourne, Kamath, and Khan

In numbered paragraphs 9-13 on pages 5-6 of the Final Office Action, claims 50, 53-55, 60, 61, 66, 72-75, 77 and 79 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the proposed combination of Eder and Whitbourne, further in view of U.S. Patent No. 6,335,029 to Kamath *et al.* ("Kamath") and U.S. Patent No. 5,589,120 to Khan *et al.* The Appellant respectfully traverses the rejection and hereby appeals the same.

Neither one of Kamath nor Khan is believed to remedy the above-noted deficiencies of Eder and/or Whitbourne, particularly with regard to the feature of a coating, formulation, or containing means "bridging from one edge or surface to another across an opening" as substantially recited in at least claims 23, 43, 45, 50, 61, and 77. With regard to Kamath, the Final Office Action cites a portion which purportedly describes an "implantable medical device having a structure adapted for introduction into a patient, e.g., a stent, coil, catheter, etc.," and which may have "at least one composite layer of a bioactive agent and a polymer material and at least one barrier layer positioned over the composite layer or layers." Kamath, column 2, lines 45-52. This reference adds nothing to Whitbourne, and does not teach or suggest a coating bridging from an edge or surface to another across an opening. Similarly, Khan is purportedly directed to a process of making a shaped tip on a catheter (*see* Title) and does not teach or suggest a coating bridging from an edge or surface to another across an opening. Claims 53-55, 60, 66, 72-75, and 79 depend variously from at least one of claims 23, 43, 45, 50, 61, and 77 and are, therefore, believed to be allowable for at least the same reasons. Reversal of the rejection is respectfully requested.

VIII. CONCLUSION

In summary, the Appellant respectfully requests reversal of the rejection of claims 23-67 and 69-83 under 35 U.S.C. § 103(a).

Respectfully submitted,

Date: May 4, 2009

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DC2-1030657v1

IX. CLAIMS APPENDIX - 37 C.F.R. § 41.37(c)(1)(viii)

Claims 1-22. ***(Canceled)***

Claim 23. ***(Previously Presented)*** A medicated device comprising:

a substrate comprising adjacent edges or surfaces in close proximity to each other defining an opening; and

a coating bridging from one edge or surface to another across the opening, and said coating comprising at least one polymer and at least one therapeutic agent,

said therapeutic agent being at a loading of at least about 100 micrograms per square centimeter of coating.

Claim 24. ***(Previously Presented)*** The medicated device of claim 23, said therapeutic agent being at a loading of at least about 500 micrograms per square centimeter of coating.

Claim 25. ***(Previously Presented)*** The medicated device of claim 61, said coating comprising a bond coat layer and a layer comprising the therapeutic agent.

Claim 26. ***(Previously Presented)*** The medicated device of claim 61, said substrate comprising a wire configured into a coil.

Claim 27. ***(Previously Presented)*** The medicated device of claim 26, said coil having open windings.

Claim 28. ***(Previously Presented)*** The medicated device of claim 61, said substrate selected from the group consisting of perforated wafers and wire meshes.

Claim 29. ***(Previously Presented)*** The medicated device of claim 61, said substrate selected from the group consisting of mandrels, beads, cylinders, egg-shaped articles, spheres, coiled articles, straight articles, threads, wires, pellets, tubing, and stents.

Claim 30. ***(Previously Presented)*** The medicated device of claim 61, wherein when said device is implanted in a tissue, a therapeutic amount of said therapeutic agent diffuses at least about one centimeter from said device.

Claim 31. ***(Previously Presented)*** The medicated device of claim 61, wherein in a zone of inhibition test, effective amounts of the therapeutic agent diffuse at least about one half centimeter from said device.

Claim 32. ***(Previously Presented)*** The medicated device of claim 61, said therapeutic agent being one or more selected from the group consisting of an antibiotic agent, an anticancer agent, an antiangiogenic agent, an antimicrobial agent, an antiviral agent, and an antithrombogenic agent.

Claim 33. ***(Previously Presented)*** The medicated device of claim 61, said therapeutic agent being one or more selected from the group consisting of docetaxel, fluorouracil, doxarubicin, cisplatin, mitomycin, peplomycin, merbarone, minocycline, penicillins, cephalosporins, fluoroquinalones, tetracyclines, Chloramphenicol, Polymixin B sulfate, Bacitracin zinc, aminoglycosides, clindamycin, lincomycin, thymol, silver

compounds, benzethonium chloride, stearalkonium chloride, 1,2-benzisothiazolin-3-one, triclosan, polyhexa-methylene biguanide hydrochloride, heparin sodium, heparin complexed with a quaternary ammonium compound, heparin complexed with benzalkonium chloride, heparin complexed with stearalkonium chloride, heparin complexed with tridodecylmethylammonium chloride, hirudin, sugars, and aspirin.

Claim 34. ***(Previously Presented)*** The medicated device of claim 61, said therapeutic agent being one or more selected from the group consisting of rifamycin, gentamicin laurylsulfate, polyhexa-methylene biguanide hydrochloride, benzalkonium chloride, 2-bromo-2-nitropropane-1,3-diol, silver nitrate, and methotrexate.

Claim 35. ***(Previously Presented)*** The medicated device of claim 61, said therapeutic agent comprising heparin and at least one additional agent.

Claim 36. ***(Previously Presented)*** The medicated device of claim 61, said coating comprising at least one hydrophobic polymer and at least one hydrophilic polymer.

Claim 37. ***(Previously Presented)*** The medicated device of claim 61, said coating comprising a first polymer and a second polymer, said first polymer being more hydrophilic than said second polymer.

Claim 38. ***(Previously Presented)*** The medicated device of claim 36, said hydrophilic polymer comprising a polymer being one or more selected from the group consisting of a polyacrylamide/ethylene glycol copolymer, a polyacrylamide/polyethylene

oxide copolymer, polyvinylpyrrolidone, polyvinylpyrrolidone vinylacetate copolymer, a polyethylene glycol, and a polyethylene oxide.

Claim 39. ***(Previously Presented)*** The medicated device of claim 36, said hydrophobic polymer comprising an acrylate/carboxyl copolymer, a cellulose ester polymer, cellulose nitrate, a polyurethane polymer, an acrylate polymer, and an acrylate copolymer.

Claim 40. ***(Previously Presented)*** The medicated device of claim 36, said coating comprising at least as much hydrophobic polymer as hydrophilic polymer by weight.

Claim 41. ***(Previously Presented)*** The medicated device of claim 36, said coating comprising hydrophobic polymer and hydrophilic polymer in a weight ratio in the range of from about 1.5:1 to about 7:1.

Claim 42. ***(Previously Presented)*** The medicated device of claim 61, said coating comprising an acrylate polymer and polyvinylpyrrolidone/vinyl acetate copolymer in a weight ratio in the range of from about 1.5:1 to about 7:1.

Claim 43. ***(Previously Presented)*** A method for making a medicated device, comprising the steps of:

providing a substrate comprising edges or surfaces in close proximity to each other defining an opening;

providing a coating material comprising at least one polymer and at least one therapeutic agent; and,

applying the coating material to said substrate to produce a coating bridging from one edge or surface to another across the opening, the therapeutic agent being at a loading of at least about 5 micrograms per square centimeter of coating material.

Claim 44. ***(Previously Presented)*** The method of claim 43, comprising applying a polymeric coating sheath to said substrate, and applying to said sheath a layer of said coating material.

Claim 45. ***(Previously Presented)*** A method of providing a therapeutic agent to a target tissue, comprising the steps of:

providing a medicated device comprising a substrate comprising adjacent edges or surfaces in close proximity to each other defining an opening, a coating bridging from one edge or surface to another across the opening, and said coating containing at least one polymer and at least one therapeutic agent and comprising one or more layers; and,

inserting the medicated device into the target tissue to provide therapeutic benefit, wherein a therapeutic amount of said therapeutic agent diffuses into the tissue at least about one centimeter from said device.

Claim 46. ***(Previously Presented)*** The method of claim 45, the tissue comprising a tumor or a lesion.

Claim 47. ***(Previously Presented)*** The method of claim 45, said inserting comprising inserting the medicated device into a tumor, wherein said therapeutic agent comprises an anti-cancer drug.

Claim 48. ***(Previously Presented)*** The method of claim 45, said inserting comprising inserting the medicated device into a lesion, wherein said therapeutic agent comprises an antibiotic.

Claim 49. ***(Previously Presented)*** The method of claim 45, further comprising inserting the medicated device using a trochar or catheter.

Claim 50. ***(Previously Presented)*** A medicated device comprising:

a substrate suitable for implantation into a patient's body and comprising adjacent edges or surfaces in close proximity to each other defining an opening; and

a formulation comprising at least one polymer and at least one therapeutic agent, the formulation bridging from one edge or surface to another across the opening, the therapeutic agent being at a loading sufficient to deliver a therapeutically effective quantity of the therapeutic agent when implanted in the patient's body.

Claim 51. ***(Previously Presented)*** The device of claim 50 wherein the substrate has an open, perforated, or mesh structure providing support for the formulation.

Claim 52. ***(Previously Presented)*** The device of claim 50 wherein the substrate is a stent.

Claim 53. ***(Previously Presented)*** The device of claim 50 wherein the therapeutic agent comprises paclitaxel.

Claim 54. ***(Previously Presented)*** The device of claim 50 wherein the substrate is a stent and the therapeutic agent comprises paclitaxel.

Claim 55. ***(Previously Presented)*** The device of claim 54 wherein the stent elutes about 10% of the paclitaxel over about 14 days.

Claim 56. ***(Previously Presented)*** The medicated device of claim 23, said substrate having a shape selected from the group consisting of mandrels, beads, egg-shapes, spheres, and threads.

Claim 57. ***(Previously Presented)*** The medicated device of claim 23, said therapeutic agent being an antiangiogenic agent.

Claim 58. ***(Previously Presented)*** The medicated device of claim 23, said therapeutic agent being an antiviral agent.

Claim 59. ***(Previously Presented)*** The medicated device of claim 23, said therapeutic agent being one or more selected from the group consisting of docetaxel, doxarubicin, mitomycin, peplomycin, minocycline, penicillins, cephalosporins, fluoroquinalones, tetracyclines, Chloramphenicol, Polymixin B sulfate, Bacitracin zinc, clindamycin, lincomycin, 1,2-benzisothiazolin-3-one, triclosan, polyhexa-methylene biguanide hydrochloride, hirudin, and aspirin.

Claim 60. ***(Previously Presented)*** The medicated device of claim 23, said therapeutic agent being one or more selected from the group consisting of polyhexa-methylene biguanide hydrochloride and 2-bromo-2-nitropropane-1,3-diol.

Claim 61. ***(Previously Presented)*** A medicated device comprising:

a substrate comprising adjacent edges or surfaces in close proximity to each other defining an opening; and

a coating bridging from one edge or surface of the substrate to another across the opening, and said coating comprising at least one polymer and at least one therapeutic agent at a loading sufficient to deliver a therapeutically effective quantity of the therapeutic agent when implanted in a patient's body.

Claim 62. ***(Previously Presented)*** The medicated device of claim 61, wherein the therapeutic agent comprises an antithrombogenic and/or an antiangiogenic agent in an effective amount.

Claim 63. ***(Previously Presented)*** The medicated device of claim 61, wherein said coating comprises at least one antithrombogenic agent.

Claim 64. ***(Previously Presented)*** The medicated device of claim 61, wherein said coating comprises at least one antiangiogenic agent.

Claim 65. ***(Previously Presented)*** The medicated device of claim 61, wherein said substrate comprises metal.

Claim 66. ***(Previously Presented)*** The medicated device of claim 61, wherein said coating comprises paclitaxel.

Claim 67. ***(Previously Presented)*** The medicated device of claim 65, wherein said substrate is a stent.

Claim 68. ***(Canceled)***

Claim 69. ***(Previously Presented)*** The method of claim 43, wherein said therapeutic agent is in the coating at a loading of at least about 100 micrograms per square centimeter of coating.

Claim 70. ***(Previously Presented)*** The method of claim 45, wherein said therapeutic agent is at a loading of at least about 100 micrograms per square centimeter of coating.

Claim 71. ***(Previously Presented)*** The medicated device of claim 50, wherein said therapeutic agent is at a loading of at least about 100 micrograms per square centimeter of the coating.

Claim 72. ***(Previously Presented)*** The medicated device of claim 23, said therapeutic agent comprising paclitaxel.

Claim 73. ***(Previously Presented)*** The medicated device of claim 61, said therapeutic agent comprising paclitaxel.

Claim 74. ***(Previously Presented)*** The medicated device of claim 61, said therapeutic agent selected from the group consisting of heparin sodium and heparin complexed with a quaternary ammonium compound.

Claim 75. ***(Previously Presented)*** The medicated device of claim 61, wherein the at least one polymer comprises a poly(L-lactic acid) blend.

Claim 76. ***(Previously Presented)*** The medicated device of claim 61, wherein the at least one polymer comprises a polyester.

Claim 77. ***(Previously Presented)*** A medicated device, comprising:

a therapeutic agent;

means for containing the therapeutic agent; and

means for providing structural support to the containing means, wherein the containing means bridges from one portion of the structural support providing means to another portion of the structural support providing means, wherein the therapeutic agent is at a loading sufficient to deliver a therapeutically effective quantity of the therapeutic agent in a patient's body when the device is implanted therein.

Claim 78. ***(Previously Presented)*** The medicated device of claim 77, wherein the structural support providing means is selected from the group consisting of a perforated wafer, a wire mesh, and a stent.

Claim 79. ***(Previously Presented)*** The medicated device of claim 77, wherein the

therapeutic agent comprises paclitaxel.

Claim 80. ***(Previously Presented)*** The medicated device of claim 77, the therapeutic agent being at a loading of at least about 5 micrograms per square centimeter of the containing means.

Claim 81. ***(Previously Presented)*** The medicated device of claim 77, the therapeutic agent being at a loading of at least about 50 micrograms per square centimeter of the containing means.

Claim 82. ***(Previously Presented)*** The medicated device of claim 77, the therapeutic agent being at a loading of at least about 100 micrograms per square centimeter of the containing means.

Claim 83. ***(Previously Presented)*** The medicated device of claim 77, the therapeutic agent being at a loading of at least about 500 micrograms per square centimeter of the containing means.

X. EVIDENCE APPENDIX - 37 C.F.R. § 41.37(c)(1)(ix)

- The Declaration of Ms. Alexandra Chamberlain submitted February 22, 2008 pursuant to 37 C.F.R. § 1.132 is attached hereto. Ms. Chamberlain's Declaration was entered in the record by the Examiner on or before May 28, 2008, as indicated on page 2 of the Final Office Action of the same date.
    - APPENDIX A – CV of Declarant Ms. Alexandra M. Chamberlain
    - APPENDIX B –Revised FIG. 2 of Eder referenced in Ms. Chamberlain's Declaration.

- U.S. Patent No. 5,980,550 to Eder *et al.* (copy attached)

XI. RELATED PROCEEDINGS APPENDIX - 37 C.F.R. § 41.37(c)(1)(x)

NONE

XII. TABLE OF CASES

Page / Case Name

12 / *In re Aslanian*, 590 F.2d 911, 914, 200 USPQ (BNA) 500 (CCPA 1979)

12 / *In re Baum*, 374 F.2d 1004, 1009, 153 USPQ 190, 195 (CCPA 1967)

12 / *Ex Parte Deok-Kee Kim et al.*, 2009 WL 505513 at *5 (Bd.Pat.App. & Interf. Feb. 26, 2009)